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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

SCHMIDT

Serial No.: 10/655,889

Filed: September 4, 2003

Atty. File No.: 2848-28-PUS-1-1

For: "USE OF NEUROTOXIN THERAPY  
FOR TREATMENT OF UROLOGICAL-  
NEUROLOGICAL DISORDERS  
ASSOCIATED WITH PROSTATE  
CANCER"

Mail Stop: Amendments  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450



Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE  
STATEMENT

<p>CERTIFICATE OF MAILING</p> <p>I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313 ON THIS <u>23</u> DAY OF <u>June</u>, 2004.</p> <p>SHERIDAN ROSS P.C.</p> <p>BY: <u>Chasity C. Rossum</u> Chasity C. Rossum</p>
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Sir:

The references cited on attached Form PTO-1449 are being called to the attention of the Examiner.

☒ Copies of only the cited non-patent references identified by an asterisk (\*) are enclosed

herewith as they were not previously submitted in a prior application.

☐ Copies of the cited U.S. patents and/or U.S. patent application publications are not enclosed in accordance with the waiver dated July 11, 2003, whereby patent applications filed after June 30, 2003 and international applications that have entered the national stage under 35 U.S.C. § 371 after June 30, 2003 need not submit copies of U.S. patents and U.S. patent application publications.

☒ Copies of the cited references are not enclosed, in accordance with 37 C.F.R. 1.98(d), because the references were submitted to the U.S. Patent and Trademark Office in prior application Serial No. 09/978,982 filed October 15, 2001 (now U.S. Pat. No. 6,667,041), which is relied upon for an earlier filing date under 35 U.S.C. § 120.

☐ To the best of applicants' belief, the pertinence of the foreign-language references are believed to be summarized in the attached English abstracts and in the figures, although applicants do not necessarily vouch for the accuracy of the translation.

☐ Examiner's attention is directed to the following co-pending application(s) for which priority is not being claimed, copies have been or are being submitted:

Serial No. \_\_\_\_\_ filed \_\_\_\_\_ (Atty. Dckt. No. \_\_\_\_\_)

☐ Examiner's attention is directed to the following co-pending application(s), to which the current application claims priority, copies of at least the claims for such pending application are provided or have been provided:

Serial No. \_\_\_\_\_ filed \_\_\_\_\_ (Atty. Dckt. No. \_\_\_\_\_)

Submission of the above information is not intended as an admission that any item is citable under the statutes or rules to support a rejection, that any item disclosed represents analogous art, or that those skilled in the art would refer to or recognize the pertinence of any reference without the benefit of hindsight, nor should an inference be drawn as to the pertinence of the references based on the order in which they are presented. Submission of this statement should not be taken as an indication that a search has been conducted, or that no better art exists.

It is respectfully requested that the cited information be expressly considered during the prosecution of this application and the references made of record therein.

### FEES

<input checked="" type="checkbox"/>	<p><b>37 CFR 1.97(b):</b> No fee is believed due in connection with this submission, because the information disclosure statement submitted herewith is satisfies one of the following conditions ("X" indicates satisfaction):</p> <div style="margin-left: 20px;"> <input type="checkbox"/> Within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d), or  <input type="checkbox"/> Within three months of the date of entry into the national stage of an international application as set forth in 37 CFR 1.491 or  <input checked="" type="checkbox"/> Before the mailing date of a first Office Action on the merits, or  <input type="checkbox"/> Before the mailing of a first Office action after the filing of a Request for Continued Examination (RCE) under 37 CFR 1.114.         </div> <p>Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970.</p>
<input type="checkbox"/>	<p><b>37 CFR 1.97(c):</b> The information disclosure statement transmitted herewith is being filed after all the above conditions (37 CFR 1.97(b)), but before the mailing date of one of the following conditions:</p> <div style="margin-left: 40px;">             (1) a final action under 37 C.F.R. 1.113 or              (2) a notice of allowance under 37 C.F.R. 1.311, or              (3) an action that otherwise closes prosecution in the application.           </div> <p>This Information Disclosure Statement is accompanied by:</p> <div style="margin-left: 20px;"> <input type="checkbox"/> A Certification (below) as specified by 37 C.F.R. 1.97(e). Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970.  <div style="text-align: center; margin: 5px 0;">OR</div> <input type="checkbox"/> A check in the amount of \$180.00 for the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement. Please credit any overpayment or charge any underpayment to Deposit Account No. 19-1970.           </div>
<input type="checkbox"/>	<p><b>37 CFR 1.97(d):</b> This Information Disclosure Statement is being submitted after the period specified in 37 CFR 1.97(c).</p> <div style="margin-left: 20px;"> <input type="checkbox"/> This information Disclosure Statement includes a Certification (below) as specified by 37 C.F.R. 1.97(e)  <div style="text-align: center; margin: 5px 0;">AND</div> <input type="checkbox"/> Applicants hereby requests consideration of the reference(s) disclosed herein. Enclosed is the fee in the amount of \$180.00 under 37 C.F.R. 1.17(p). Please credit any overpayment or charge any underpayment to Deposit Account No. 19-1970. Please credit any overpayment or charge any underpayment to Deposit Account No. 19-1970. Election to pay the fee should not be taken as an indication that applicant(s) cannot execute a certification.           </div>



**Certification (37 C.F.R. 1.97(e))**  
(Applicable only if checked)

☐ The undersigned certifies that:

☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(1).

☐ A copy of the communication from the foreign patent office is enclosed.

OR

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(2).

Respectfully submitted,

SHERIDAN ROSS, P.C.

By: \_\_\_\_\_

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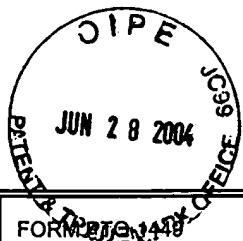
TELEPHONE: 303-863-2975

FAX: 303-863-0223

Date: \_\_\_\_\_

*June 23, 2004*

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SHEET 1 OF 3

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	ATTY. DOCKET NO. 2848-28-PUS-1-1	SERIAL NO. 10/655,889
	APPLICANT SCHMIDT	
	FILING DATE September 4, 2003	GROUP ART 1651

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROP.
	1	6,365,164	4-2-2002	Schmidt	424	239.1	
	2	5,837,265	11-17-1998	Montal et al.	424	239.1	
	3	5,437,291	8/1/95	Pasricha et al.	128	898	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
	4	WO 99/03483	1/1999	PCT				

## OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

5	* "AFUD Prostate Cancer Treatment: Treatment"; <i>American Foundation for Urologic Disease</i> ; (at least as early as August 5, 2003)
6	* Bardsley; "The Neurogenic Bladder"; <i>Art &amp; Science Continence</i> ; (January 7, 2000); pp. 39-41
7	* Burnstein et al.; "Prostatitis: A Difficult Diagnosis"; <i>DeKalb Clinic Urology</i> ; (at least as early as August 20, 2003); 3 pp.
8	Bruschini et al., "Neurologic Control of Prostatic Secretion in the Dog"; <i>Invest. Urol.</i> , 15(4):288-290 (January 1978)
9	* "Continence Management"; <i>The Prostate Cancer Charity</i> ; (at least as early as August 8, 2003); 6 pp.
10	* Crawford; "Prostate Cancer"; <i>Best Doctors</i> ; (June 7, 2000); 6 pp.
11	Downie et al., "Evidence for a Spinal Site of Action of Clonidine on Somatic and Viscerosomatic Reflex Activity Evoked on the Pudendal Nerve in Cats"; <i>J. Pharmacol. Exp. Ther.</i> , 246(1):352-358 (May 1988)
12	Dykstra et al., "Treatment of Detrusor-Sphincter Dyssynergia with Botulinum A Toxin: A Double-Blind Study"; <i>Arch. Phys. Med. Rehabil.</i> , 71:24-26 (January 1990)

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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13	* Epstein; "Gleason Score 2 - 4 Adenocarcinoma of the Prostate on Needle Biopsy"; <i>American Journal of Surgical Pathology</i> ; (2000) Vol. 24(4); pp. 477-78
14	Håkanson et al., "Multiple Tachykinin Pools in Sensory Nerve Fibres in the Rabbit Iris"; <i>Neuroscience</i> , 21(3):943-950 (1987)
15	Higgins et al., "Studies on the Structure and Intrinsic Innervation of the Normal Human Prostate"; <i>Prostate Suppl.</i> , 2:5-16 (1989)
16	* "Inconsistence and the Prostate"; <i>Phoenix5</i> ; (at least as early as August 5, 2003); 11 pp.
17	Ishizuka et al., "Urodynamic Effects of Intravesical Resiniferatoxin and Capsaicin in Conscious Rats With and Without Outflow Obstruction"; <i>J. Urology</i> , 154:611-616 (August 1995)
18	Joo et al., "Initial North American Experience with Botulinum Toxin Type A for Treatment of Anismus"; <i>Dis. Colon. Rectum</i> , 39(10):1107-1111 (October 1996)
19	Lepor "Role of Long-Acting Selective Alpha-1 Blockers in the Treatment of Benign Prostatic Hyperplasia"; <i>Urol. Clin. North Am.</i> , 17(3):651-658 (August 1990)
20	Maggi et al., "Cystometric Evidence That Capsaicin-Sensitive Nerves Modulate the Afferent Branch of Micturition Reflex in Humans"; <i>J. Urol.</i> , 142:150-154 (July 1989)
21	* Marieb; "Chapter 13: Peripheral Nervous System and Reflex Activity"; <i>Human Anatomy and Physiology</i> , 5 <sup>th</sup> Ed.; (at least as early as August 8, 2003) 5 pp.
22	Mocchetti, "Pharmacology of Neuronal Gene Expression"; <i>Pharmacol. Res.</i> , 21(Suppl. 2):85-95 (1989)
23	* Peak; "Understanding Continence"; <i>The Interdisciplinary Journal of Rehabilitation</i> ; (March 2002); 9 pp.
24	* "Prostate Cancer: Prostate Cancer Transrectal Biopsies"; (at least as early as August 20, 2003); 9 pp.
25	* "Prostate Cancer: Tumor Grading"; <i>UPMC Cancer Centers</i> ; (2003); 2 pp.
26	* "Prostate Cancer: What are the Treatment Options?"; <i>NSW Health</i> ; (January 4, 2002); 2 pp.
27	* "Prostate Cancer (PDQ®): Treatment"; <i>National Cancer Institute</i> ; (July 17, 2003); 11 pp.
28	* "Prostate Gland and Urinary Problems"; <i>Better Health Channel</i> ; (October 10, 2001); 10 pp.
29	Schurch et al., <i>J. Urol.</i> , 155:1023-1029 (1996)
30	* Strum; "Is There a Correct Way to Treat Prostate Cancer"; <i>Prostate Cancer Research Institute</i> ; 28 pp. (at least as early as 9/12/2000)
31	* Strum; "Predictive and Prognostic Information in the Counseling of Patients Recently Diagnosed with Prostate Cancer"; <i>The Prostate Cancer Research Institute</i> ; (at least as early as September 12, 2000); 21 pp.
32	* "The Side Effects of Treatment"; <i>Varian Medical System</i> ; (1999-2003); 2 pp.
33	Tim et al., <i>Botulinum Toxin Therapy</i> , 9(6):327-332 (1992)
34	* "Treating Prostate Disease"; <i>The Cleveland Clinic</i> ; (January 28, 1999); 3 pp.

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	35	* "Treatment for Localized Disease: Observation and Monitoring of PSA"; <i>Prostate Cancer Research Institute</i> ; (at least as early as August 11, 2003); 1 p.
	36	* "Questions and Answers About the Prostate-Specific Antigen (PSA) Test"; <i>National Cancer Institute</i> ; (January 11, 2001); 5 pp.
	37	* "Understanding Gleason Grading"; <i>Phoenix5</i> ; (May 14, 1997); 8 pp.

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